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| 10/776,311 | 02/11/2004 | Anthony J. Kinney | BB1538USNA | 4023 |
| 23906 7590 07/16/2008 E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1122B 4417 LANCASTER PIKE WILMINGTON, DE 19805 | | | | |
| EXAMINER FOX, DAVID T | | | | |
| ART UNIT 1638 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

Office Action Summary

Application No.

10/776,311

Applicant(s)

KINNEY ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 12, 16, 21-26 and 140 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 and 140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 12, 16 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Objection

Claim 1, submitted with the amendment of 17 April 2008, does not comply with 37 CFR 1.121(c) because it recites an improper status identifier. The claim recites "(amended)", but it should recite "(currently amended)". In the interest of compact prosecution, the claim has been treated on the merits.

Withdrawn Rejections

Applicant's amendments of 17 April 2008 have overcome the obviousness-type double patenting rejection, the written description rejection, and the first obviousness rejection set forth on pages 4-7 of the Office action of 01 April 2008.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Telephonic Interview of 16 April 2008

During the telephonic interview of 16 April 2008, the Examiner indicated that a claim amendment proposed by Applicant, now incorporated into amended claim 1, might result in the withdrawal of both of the rejections under 35 USC 112, first paragraph. Upon further consideration, the Examiner has decided to maintain the enablement rejection.

Enablement

Claims 1, 12, 16 and 26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to oilseed plants which produce mature seeds with oil comprising at least 1% of at least one of EPA, DPA or DHA, wherein said plants have been transformed with at least two desaturase genes

and at least one corresponding elongase gene from the same pathway as at least one of the desaturase genes; does not reasonably provide enablement for claims broadly drawn to any oilseed plant which produces the claimed levels of EPA, DPA or DHA and which merely comprises at least one desaturase gene and at least one elongase gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on page 3 of the Office action of 01 April 2008 for claims 1, 11-12, 16-18, 26-28 and 141.

Applicant's arguments filed 17 April 2008 have been fully considered but they are not persuasive. Applicant urges that some oilseed crops, such as borage, blackcurrant and hemp; naturally produce stearidonic acid (SDA) which contains 18 carbon molecules and 4 double bonds, so that only one heterologous elongase gene and one heterologous desaturase gene would be required.

The Examiner maintains that no evidence, in the form of published articles or other printed literature, has been presented to support this asserted characteristic of borage and other oilseed crops. Moreover, it is unclear whether all of the crops listed, particularly blackcurrant, are considered "oilseed" crops. Furthermore, the claims do not specify that the elongase correspond to at least one of the desaturases present, e.g. a delta-6 elongase and a delta-6 desaturase, wherein such correspondence appears to be required for proper substrate processing.

Obviousness

Claims 1, 12, 16 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Knutzon et al (US 6,075,183) in view of ABBOTT LABORATORIES (WO 02/08041), further in view of each of Mukherji et al (US 7,211,656) or Browse et al (US 6,884,921), as stated on pages 8-10 of the Office action of 01 April 2008 for claims 1, 11-12, 16-18, 26-28 and 141.

Applicant's arguments filed 17 April 2008 have been fully considered but they are not persuasive. Applicant urges that the production of EPA or DHA in plant seed oil, when utilizing the transgenes taught by the cited combination of references, was unexpected at the time of the invention; given the understanding in the prior art that an acyltransferase gene was needed to transport the fatty acid substrates to and from the cell membrane, for the combined action of the desaturase and the elongase enzymes which were localized in different cellular components. Applicant cites Robert et al (2006), a Review article, and Wu et al (2005), to support this position.

The Examiner disagrees that the artisan of ordinary skill would not have expected the production of EPA or DHA in seed oil at the time of the invention, in the absence of an acyltransferase. The Examiner has reviewed Wu et al, Robert et al, Abbadi et al (2004, mentioned in the telephonic interview of 16 April 2008, and cited by Robert et al on page 105, paragraph bridging the columns), and Qi et al (cited in Robert et al as being the first published demonstration of EPA production in transformed plants; see, e.g., page 104 of Robert et al, column 1, bottom paragraph). The cited references

do not support Applicant's assertions regarding the state of the art at the time of the instant invention, as detailed below.

Qi et al (June 2004) demonstrate high levels of EPA production in transgenic plants, when transformed with a combination of two desaturase genes and one elongase gene, namely a delta-9 elongase, a delta-8 desaturase from the same pathway, and a delta-5 desaturase gene (see, e.g., page 740; page 741, Table 1 and column 1). Qi et al obtained 3% EPA in the leaves of transgenic plants, since they utilized a constitutive promoter (see, e.g., Table 1). No acyltransferase gene was reported. Thus, the earliest report of EPA production in transformed plants did not lead the artisan of ordinary skill to expect failure in the absence of a heterologous acyltransferase gene. Moreover, Qi et al suggested the use of a seed-specific promoter to obtain high levels of EPA in the seed oil (see, e.g., page 743, column 2, penultimate paragraph), as taught by the references cited by the Examiner. Note that Qi et al was published prior to the publication of Applicant's PCT Application (August 2004).

Abbadi et al (October 2004) utilized two desaturase genes, a delta-5 and delta-6 desaturase, and one delta-6 elongase gene, under the control of seed-specific promoters, for the production of up to 1% EPA in transgenic flax seeds (see, e.g., page 2735, Figure 1 and paragraph bridging the columns; page 2736, Figure 2; page 2738, Table 1), which is commensurate with the instantly claimed EPA levels. Although Abbadi et al later suggest the use of an acyltransferase gene as *one of several* options for obtaining *even higher* EPA levels (see, e.g., page 2745, column 1, first full

paragraph, where *another* option is suggested), it is noted that the instant claims encompass the EPA level taught by Abbadi et al.

See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Wu et al (2005) utilized several combinations of constructs which comprised a seed-specific napin promoter and various coding sequences involved in fatty acid biosynthesis, starting with a construct comprising two desaturase genes and one elongase gene (BJ3), then adding another desaturase gene (BJ4), then adding another elongase gene (BJ5), then adding another desaturase gene (BJ6), then finally adding several more genes including an acyltransferase gene and a gene encoding an elongase that acts on both C-18 and C-20 fatty acids (BJ9). See page 1013, column 2 through page 1014, column 1 of Wu et al. Note that Wu et al *did not start* with an acyltransferase gene, and only added one in their *fifth* construct.

Wu et al obtained at least 1% EPA (as instantly claimed) in the oil of seeds produced by plants transformed with *every* construct they evaluated. See page 1015, Table 1. The 3-gene construct (BJ3) produced plants with an average of 0.9 % EPA, with individual plants producing seed with as much as 1.1%. The 4-gene construct (BJ4) produced plants with an average of 1.5% EPA, with an upper limit of 1.7. The 5-gene construct (BJ5) produced plants with an average of 2.3% EPA, with an upper limit of 2.7%. The 6- gene construct (BJ6) produced plants with an average of 8.5% EPA, with an upper limit of 11%. Finally, BJ9, the 9-gene construct (which included the

acyltransferase gene and also the versatile elongase gene) produced plants with an average of 10.9% EPA, with an upper limit of 15%; and 0.2% DHA with an upper limit of 1.5%.

Thus, Wu et al demonstrated EPA levels commensurate with the claimed EPA levels, *in the absence of any acyltransferase* gene. Moreover, Wu et al state that the improved EPA levels in the 9-gene construct could have been due to *either* the acyltransferase gene *or* the versatile elongase gene (see, e.g., page 1014, column 1, second full paragraph, last sentence). Thus, the state of the art up to and after the instant invention did not point to the absolute requirement for an acyltransferase gene.

Robert et al (2006) report that Robert et al (2005) utilized a gene encoding a dual activity desaturase, a delta-6 elongase gene, a delta-5 elongase gene, and a delta-4 desaturase gene to obtain 2.5% EPA (see, e.g., page 105 of the Review article, column 2, bottom paragraph), which is higher than the instantly claimed levels. Thus, Robert et al (2005) did not follow the alleged state of the art which required an acyltransferase gene.

Moreover, Robert et al (2006) attribute the instant inventors' success, and Wu et al's success, to the use of *multiple* transgenes including a transgene encoding a delta-17 desaturase, which converts omega-6 fatty acids into omega-3 fatty acids (see, e.g., page 106, column 1, first two full paragraphs). However, it is noted that the instant claims do not recite a delta-17 desaturase gene or multiple genes. See *Lindner* and *Grasselli* cited above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR only.

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

/David T Fox/

Primary Examiner, Art Unit 1638

July 9, 2008